

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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SUITE 207
ARLINGTON, VIRGINIA 22202

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing (day/month/year) 12 AUG 2003	
REPLY DUE within 1 months/days from the above date of mailing (d) (PS)	
Applicant's or agent's file reference 01/22753	International application No. PCT/IL01/01080
International filing date (day/month/year) 22 November 2001 (22.11.2001)	Priority date (day/month/year) 24 November 2000 (24.11.2000)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/685, 31/215, 31/24, 31/19, 31/20, 31/12, 31/11, 31/075, 31/08; C07F 9/02; C07C 59/235, 43/11 and US Cl.: 514/76, 77, 78, 529, 534, 558, 675, 676, 693, 704, 714, 716, 723; 554/78, 79, 80, 81, 82; 562/578; 560/263, 264, 252; 568/305, 307, 413, 141, 423, 613, 622	
Applicant VASCULAR BIOGENICS, LTD.	

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 24 March 2003 (24.03.2003).

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
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Rosalynd Keys

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WRITTEN OPINION

PCT/IL01/01080

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-58, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the claims:
 pages 59-66, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the drawings:
 pages 1-9, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages none
- ☒ the claims, Nos. none
- ☒ the drawings, sheets/fig none

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
PCT/IL01/01080

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>2 and 13</u>	YES
	Claims <u>1, 3-12 and 14-22</u>	NO
Inventive Step (IS)	Claims <u>2 and 13</u>	YES
	Claims <u>1, 3-12 and 14-22</u>	NO
Industrial Applicability (IA)	Claims <u>1-22</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. Citations and Explanations:

Claims 3, 6-9, 11 and 19-22 lack novelty under PCT Article 33(2) as being anticipated by Boullier et al. (The Journal of Biological Chemistry, 31 March 200, Vol. 275, No. 13, pages 9163-9169). Boullier et al. teach the claimed composition and method at pages 9163 and 9164 (see also page 9168).

Claims 3 and 6-10 lack novelty under PCT Article 33(2) as being anticipated by Subbanagounder et al. (Circulation Research, 20 August 1999, pages 311-318).

Subbanagounder et al. teach the claimed composition (see entire document, in particular pages 311-313 and 317).

Claims 3, 6-8, 11, 12, 16 and 17 lack novelty under PCT Article 33(2) as being anticipated by Tokumura et al. (The Journal of Pharmacology and Experimental Therapeutics, July 1981, Vol. 219, No.1). Tokumura et al. teach the claimed composition and method (see entire document).

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Tokumura et al. Tokumura et al. fail to teach that the composition is packaged. However, one having ordinary skill in the art would have found it obvious to provide a packaging for the composition for ease of distribution.

Claims 3, 4, 6-9 and 11 lack an inventive step under PCT Article 33(3) as being obvious over Kawamata et al. (US Patent No. 4,614,796 A). Kawamata et al. teach solutions comprising lipids useful for hemostatic, vascular stabilization and anti-shock effects (see column 1, line 5 to column 3, line 32).

Claims 3, 6-12 and 15-18 lack novelty under PCT Article 33(2) as being anticipated by Male-Brune (US Patent No. 5,660,855 A). Male-Brune teach the claimed composition and method at column 5, line 66 to column 8, line 17.

Claims 3, 6-10, 12 and 15-18 lack novelty under PCT Article 33(2) as being anticipated by The University of British Columbia (WO 95/23592). The University of British Columbia teach the claimed composition and method at pages 7-15.

Claims 3, 6-9 and 11 lack novelty under PCT Article 33(2) as being anticipated by Hanahan et al. (US Patent No. 4,329,302 A).

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Hanahan et al. teach the claimed composition at column 2, line 10 to column 5, line 58.

Claims 1, 3 and 5-11 lack novelty under PCT Article 33(2) as being anticipated by Wissner et al. (US Patent No. 4,827,011). Wissner et al. teach the claimed composition at column 1, line 5 to column 2, line 46.

Claims 12 and 14-18 lack an inventive step under PCT Article 33(3) as being obvious over Wissner et al. Wissner et al. do not explicitly teach the claimed method. However, Wissner et al. inherently teach the claimed method, since Wissner et al. teach treatment of hypertension, which if left untreated could lead to left ventricular failure, myocardial infarction, cerebral hemorrhage or infarction, and coronary or cerebral atherosclerosis (see column 1, lines 11-25).

Claims 3 and 12 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the composition of claim 3 or its use for the claimed method.

Claims 1-22 meet the criteria set out in PCT Article 33(4), because the instant compounds and compositions have pharmaceutical use in the field of cardiology.

----- NEW CITATIONS -----

none